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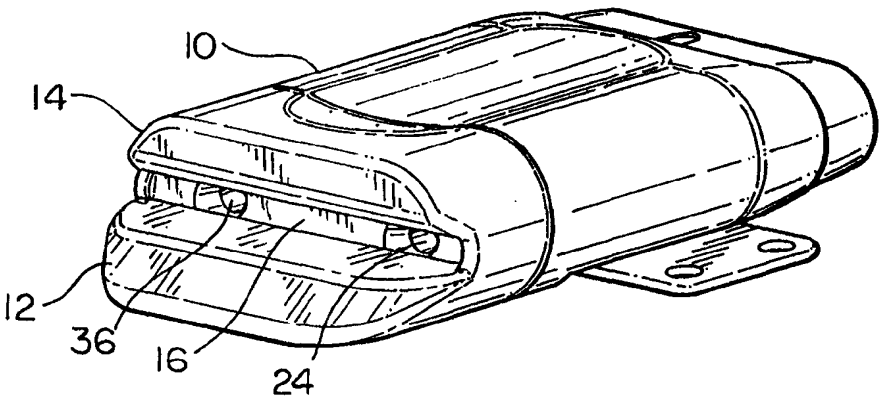
(54) Title: VASCULAR ACCESS DEVICE

(57) Abstract

A subcutaneously implantable access device is provided having a housing (10) having a first lip (12), and a second lip (14) that define an elongate trench (16). The trench (16) has an open mouth (18) defined by the first lip (12), the second lip (14), and a closed bottom (20) defined by the housing (10). The housing (10) defines a fluid path including an entrance (36, 24) and an exit (26, 38). The entrance of the fluid path is between the first lip (12), and the second lip (14) at the bottom (20) of the trench (16).



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VASCULAR ACCESS DEVICE

FIELD OF THE INVENTION

The present invention relates to a medical device and more particularly to a device for accessing the vascular system.

BACKGROUND OF THE INVENTION

Certain medical procedures, such as hemodialysis, require repeated vascular access. Known approaches for vascular access include a Scribner shunt, an arterio-venus (AV) fistula, a polytetrafluoroethylene (PFTE) graft, and catheters implanted in the jugular vein. These approaches have been less than satisfactory. For example, the Scribner shunt caused infection and clotting problems and is no longer used. The AV fistula, generally the procedure of choice, can require several months for maturation of the fistula (an arterialized vein), and is generally unsuccessful in patents having diabetes or cardiovascular disease. The PFTE graft, probably the most commonly used procedure, has serious drawbacks including stenosis and thrombosis. Finally, the percutaneous central venous catheter has serious infection and stenosis problems.

In an attempt to improve upon the above-described approaches, implantable vascular access devices have been developed that include a subcutaneous docking station or port associated with tubing in permanent communication with the vasculature. When vascular access is desired, a needle or trocar (in communication with a fluid supply and treatment apparatus) is passed through the skin proximate the docking station and mated therewith. A particular challenge associated with subcutaneously implanted devices is the difficulty in mating the needles with the docking station. Although it is possible to determined the topography of the docking station with an imaging device, in a routine hemodialysis procedure, a healthcare provider attempts to determined the topography of the device by feeling its contours through the skin. This is a difficult task and, unfortunately, mistakes are frequent and multiple skin penetrations are often made before locating an entrance aperture in the docking station for each needle. Not only is this painful for the patient, but it also

unnecessarily traumatizes the skin. Thus, if long term treatment is required, excessive skin trauma can require surgical relocation of the device to a different subcutaneous location.

Even when it is possible to properly locate an entrance aperture, it can still be difficult to insert the needle therein. Difficulties arise because skin bunches up and blocks the entrance and/or because it is difficult to precisely align the needle with the entrance. Because it can be difficult to determine whether or not the needle has been properly aligned, the needles can be bent, broken or otherwise jammed in the device.

Yet another disadvantage of known devices, particularly with respect to hemodialysis, is associated with the fluid flow path into and through the device. An angular junction between the needle and the port, and angular flow paths within a port, cause an undesirably large number of delicate blood cells to be damaged during passage through the device as the cells attempt to negotiate sharp corners and impact the walls of interior passages within the device. This has not be recognized as a problem with the known implantable ports because they were developed for non-hemodialysis applications, such as chemotherapy infusion.

In view of these and other shortcomings of known vascular access ports, it would be desirable to provide a long-term, subcutaneously-implantable device having needle entrances which are easily located and accessed, and which minimize trauma to the skin, as well as to blood cells being infused.

SUMMARY OF THE INVENTION

The present invention overcomes disadvantages of known subcutaneous ports by providing a device having a readily ascertained topography and easily accessed needle inlets. The configuration of the device also helps to minimize skin and blood cell trauma.

In an exemplary embodiment, a subcutaneous access device includes a housing with a pair of lips that define an elongate trench. At the bottom of the trench is a needle access entrance to a fluid path that extends through the housing. The trench is wider at its mouth than at the bottom of the trench and the trench is deeper than it is wide (at the bottom of the

trench). The device can include more than one fluid path and it can include a suture attachment structure.

To make the device easy to orient through a layer of skin and fat, the housing can be elongate; and to make it easy to hold in place, the housing can include a depression on its surface of the housing.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the present invention and the attendant advantages and features thereof will be more readily understood by reference to the following detailed description when it is considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a perspective view of a vascular access device in accordance with the invention;

FIG. 2 is a view of a first end of the device of FIG. 1;

FIG. 3 is a view of a first side of the device of FIG. 1, the opposite side being a mirror image;

FIG. 4 is a top view of the device of FIG. 1;

FIG. 5 is a bottom view of the device of FIG. 1;

FIG. 6 is a view of a second end of the device of FIG. 1;

FIG. 7 illustrates an alternative configuration for an entrance to a fluid path;

FIG. 8 is a schematic representation of a dialysis system, including a device in accordance with the invention, shown implanted within a human chest; and

FIG. 9 shows the system of FIG. 8 from the side.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 is a perspective view of a subcutaneously-implantable vascular access device in accordance with the invention. The device includes a housing 10 having a first lip 12 and a second lip 14 that define an elongate trench 16.

As shown in FIG. 3, the trench 16 has an open mouth 18 defined by the first lip 12 and the second lip14, and a closed bottom 20 defined by the housing 10. The housing 10 defines a fluid path 22 including an entrance 24 (shown in FIGS. 1 and 2) and an exit 26 (shown in FIG. 6). As presented in FIGS. 1 and 2, the entrance 24 of the fluid path 22 is between the first lip 12 and the second lip 14 at bottom of the trench 16.

The trench 16 has a first width between the first lip 12 and the second lip 14 at the bottom 20 of the trench, and a second width at the mouth 18 of the trench. As clearly shown in FIGS. 1 and 3, the width of the trench 16 at the mouth 18 is greater than the width of the trench at the bottom 20.

Continuing to refer to FIG. 3, the first lip 12 is provided with an inner face 26 that is substantially perpendicular to the bottom 20 of the trench 16. The second lip 14 has an inner face 28 that intersects the bottom 20 of the trench 16 at an acute angle with respect to the first lip 12. In an exemplary embodiment, the acute angle is about 30 degrees. The inner face 26 of the first lip 12 and the inner face 28 of the second lip 14 can be substantially planar. As used herein, "substantially" is used as a modifier to account for normal material and manufacturing variations that provide other than geometrically perfect forms. Although the lips can be the same dimensions, in the illustrated embodiment, the first lip 12 is larger than the second lip 14, and the second lip extends further from the housing 10 than the first lip. The edges of the lips can be radiused.

Further with respect to FIG. 3, it should be noted that the trench 16 has a depth from the mouth 18 to the bottom 20 that is greater than the width at the bottom of the trench. As shown in FIG. 2, the width of the trench 16 is substantially equivalent to the diameter of the entrance 24 of the fluid path through the housing. The entrance 24, which can be circular (to match the geometry of an access needle or trocar), does not need to be flush with the bottom 20 of the trench. A broader, shaped inlet 30 can be flush with the surface and lead to the entrance 24. The width of the trench 16 is to be distinguished from its length which is shown transversely in FIG. 2. The ends of the trench 16 can be completely open or bound

by walls or end-stops 32 and 34 that extend away from the bottom of the trench. The end-stops can be relatively short as shown, or coextensive with the lips.

Depending on the scale of the device and fluid flow requirements, more than one fluid flow path can be provided through the housing 10. For example, the exemplary device is configured with a second fluid path including an entrance 36 (shown in FIGS. 1 and 2) and an exit 38 (shown in FIG. 6). The entrance 36 of the second fluid path is between the first lip 12 and the second lip 14 at bottom of the trench 16 in a spaced-apart relationship with the entrance 24 of the first fluid path. In an exemplary embodiment, the entrances 24 and 36 are about 0.09 inches in diameter. The first fluid path and the second fluid path can be linear and parallel, or non linear and intersecting or overlapping. Accordingly, although the exits 26 and 38 are shown on the end of the housing opposite the entrances 24 and 36, the exits can be positioned at other points on the housing as desired. However, it should be recognized that the disclosed configuration provides a linear flow path from the needle through the device to the exit thereof, which greatly minimizes damage to cells being infused.

Referring now to FIGS. 4 and 5, a suture attachment structure 40 is discussed. The structure 40 provides a way to secure the vascular access device to body tissue. In the exemplary embodiment, the structure 40 is a plate secured to the housing 10. The structure can include one or more apertures 42, 44, 46, and 48 dimensioned to allow suture material to be passed therethrough. Although the structure 40 can be fixed in relation to the housing 10, it can also be movable with respect thereto. For example, the suture attachment structure 40 can be attached to the housing 10 with a pivot 50.

The thickness of a skin and fat layer can make it difficult to ascertain the topography of an implanted vascular access device. Only relatively large features can be identified by touch. Accordingly, the device is provided with a roughly rectangular housing 10 having an aspect ration that is greater than 1.5. Further, a depression 52 on the surface of the housing (shown in FIG. 4) helps to identify landmarks of the device and aids in holding in the device

in place. In an exemplary embodiment, the vascular access device is about 2 inches long, one inch wide, and one half inch thick.

FIG. 7 illustrates an alternative configuration for an entrance to the fluid path in which an entrance 54 is circular and recessed below the bottom 20 of the trench 16. A somewhat pyramidal or "mouse hole" shaped inlet 56 leads from the bottom 20 to the entrance 54.

Referring now to FIGS. 8 and 9, additional features and advantages of the vascular access device are described with respect to its functionality. FIG. 8, for example, illustrates a vascular access device 58 in accordance with the invention implanted under a region of skin and fat on the right side of a human chest. The device 58 includes a suture attachment structure 60 to which fascia below the device has been sutured. In the illustration, the device 58 is shown in a pocket of flesh created by a single incision 62. First and second cannulas 64 and 66 are shown in communication with fluid path exits. Each cannula is subcutaneous and enters a blood vessel 68. First and second needles 70 and 72 are mated with the device and third and fourth cannulas 74 and 76, respectively.

In an exemplary procedure, the device 58 is mated to one or more needles as follows. A healthcare provider palpitates the skin to determine the device orientation and the location of the mouth of the trench. The skin is stretched across the mouth of the trench so as to be taut and not draping. Because the trench is deeper than it is wide, the possibility of skin bunching-up and blocking the entrances is greatly reduced. A first needle is pushed through the skin until it strikes the inner surface of the first lip. The first needle is advanced until its tip strikes the bottom of the trench. As the first needle is advanced toward the trench, its shaft may contact the radiused leading edge of the second lip, thereby forcing the needle down toward the first lip and into an orientation that will enable entry into the fluid path entrance. After the needle has contacted the trench, and if it has not entered a fluid path entrance, the tip of the needle is slid along the bottom of the trench until it engages an entrance. The needle is then pushed into the entrance until an internal stop is encountered. If the needle is slid away from an entrance toward the outside of the trench it will abut an

end-stop, giving tactile feedback to reverse direction (toward an entrance) and preventing an undesirable needle stick to the patient. The same procedure is then repeated with additional needles, depending on the number of entrances provided in the device.

FIG. 9 shows the device 58 from the side, beneath the skin 78 and secured to the fascia 80. The needle 70 is shown having pierced the skin 78, and the tip of the needle is in contact with the inner surface 82 of the first lip 84. The surfaces which are intended for needle contact, such as the lips, trench and entrances, are preferably fabricated from a hard and smooth material so that the needle will not dig into the surfaces.

In addition to the above described features, the access port of the present invention provides increased operating time between clotting episodes, reduces infection problems, does not increase cardiac output, doesn't require maturation time, and eliminates post-dialysis bleeding and intra-dialysis bleeding.

Although the invention has been shown and described with respect to exemplary embodiments thereof, various other changes, omissions and additions in form and detail thereof may be made without departing from the spirit and scope of the invention. All references cited herein are expressly incorporated by reference in their entirety.

What is claimed is:

CLAIMS -8-

1. A subcutaneously-implantable access device comprising:

a housing having a first lip and a second lip that cooperate to define an elongate trench, the trench having an open mouth defined by the first lip and the second lip and a closed bottom defined by the housing, the housing defining a fluid path including an entrance and an exit, and the entrance of the fluid path being between the first lip and the second lip proximate the bottom of the trench.

2. The device of claim 1, wherein the trench has a width between the first lip and the second lip at the bottom of the trench and at the mouth of the trench, wherein the width at the mouth of the trench is greater than the width at the bottom of the trench.

3. The device of claim 2, wherein the first lip has an inner face that is substantially perpendicular to the bottom of the trench, and wherein the second lip has an inner face that intersects the bottom of the trench at an acute angle with respect to the first lip.

4. The device of claim 3, wherein the inner face of the first lip and the inner face of the second lip are substantially planar.

5. The device of claim 2, wherein the trench has a depth from the mouth of the trench to the bottom of the trench, and wherein the depth is greater than the width at the bottom of the trench.

6. The device of claim 5, wherein the width of the trench is substantially equivalent to the diameter of the entrance of the fluid path through the housing.

7. The device of claim 6, wherein the entrance of the fluid path is substantially circular.

8. The device of claim 2, wherein the first lip protrudes further from the housing than the second lip.

9. The device of claim 8, wherein the first lip has an inner face that is substantially perpendicular to the bottom of the trench, and wherein the second lip has an inner face that intersects the bottom of the trench at an acute angle with respect to the first lip.

10. The device of claim 9, wherein the inner face of the first lip and the inner face of the second lip are substantially planar.

11. The device of claim 1, wherein the housing further defines a second fluid path including an entrance and an exit, wherein the entrance of the second fluid path is between the first lip and the second lip proximate the bottom of the trench and spaced-apart from the entrance of the first fluid path.

12. The device of claim 11, wherein the first fluid path and the second fluid path are parallel.

13. The device of claim 12, further comprising a suture attachment structure.

14. The device of claim 13, wherein the suture attachment structure includes an apertured plate secured to the housing.

15. The device of claim 14, wherein the suture attachment structure is movable with respect to the housing.

16. The device of claim 15, wherein the suture attachment structure is pivotally attached to the housing.

17. The device of claim 16, wherein the suture attachment structure is a substantially flat plate that extends beyond opposing sides of the housing.

18. The device of claim 1, wherein the housing is elongate and further includes an elongate depression on the surface of the housing.

19. A subcutaneously-implantable access device comprising:

a housing having a first lip and a second lip that protrude from the housing to define an elongate trench, the trench having an open mouth defined by the first lip and the second lip and a closed bottom defined by the housing, the first lip protruding further from the housing than the second lip, the first lip having an inner face that is substantially planar and perpendicular to the bottom of the trench, the second lip having an inner face that is substantially planar and that intersects the bottom of the trench at an acute angle with respect to the first lip so that the mouth of the trench is wider than the bottom of the trench, the trench having a depth from the mouth of the trench to the bottom of the trench, wherein the depth of the trench is greater than the width of the trench at the bottom of the trench; and

a fluid path including an entrance and an exit defined by the housing, the entrance of the fluid path being between the first lip and the second lip proximate the bottom of the trench.

20. A subcutaneously-implantable access device comprising:

a housing having a first lip and a second lip that protrude from the housing to define an elongate trench, the trench having an open mouth defined by the first lip and the second lip and a closed bottom defined by the housing, the first lip protruding further from the housing than the second lip, the first lip having an inner face that is substantially planar and perpendicular to the bottom of the trench, the second lip having an inner face that is substantially planar and that intersects the bottom of the trench at an acute angle with respect to the first lip so that the mouth of the trench is wider than the bottom of the trench, the

trench having a depth from the mouth of the trench to the bottom of the trench, wherein the depth of the trench is greater than the width of the trench at the bottom of the trench, and a raised barrier at opposing ends of the trench between the first lip and the second lip;

a plurality of substantially parallel fluid paths, each fluid path including an entrance and an exit defined by the housing, the entrance of each fluid path being between the first lip and the second lip proximate the bottom of the trench;

an apertured plate pivotally secured to the housing and extending beyond opposing sides of the housing; and

an elongate depression on the surface of the housing.

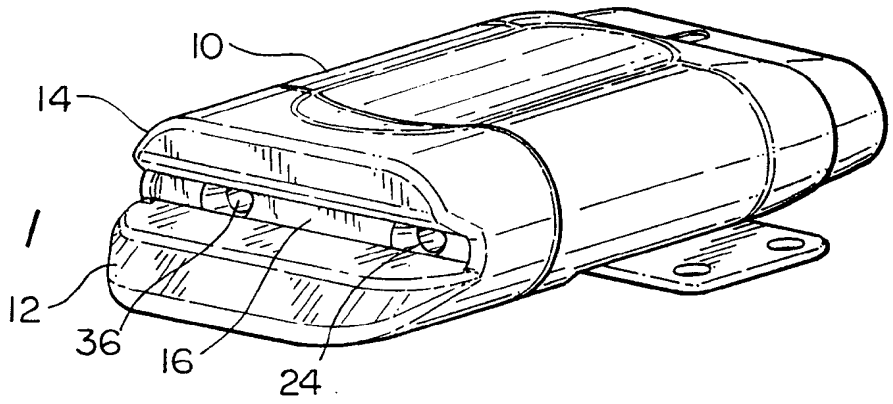

FIG. 1

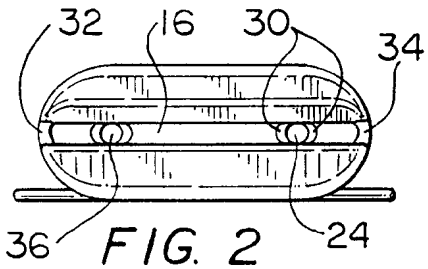

FIG. 2

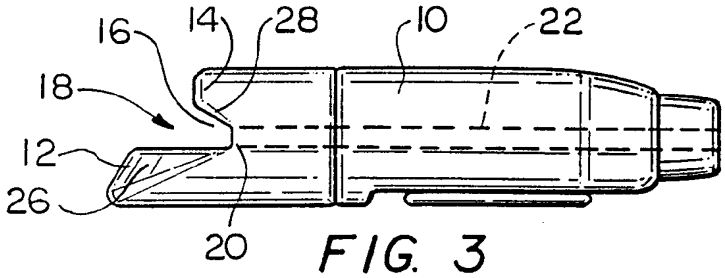

FIG. 3

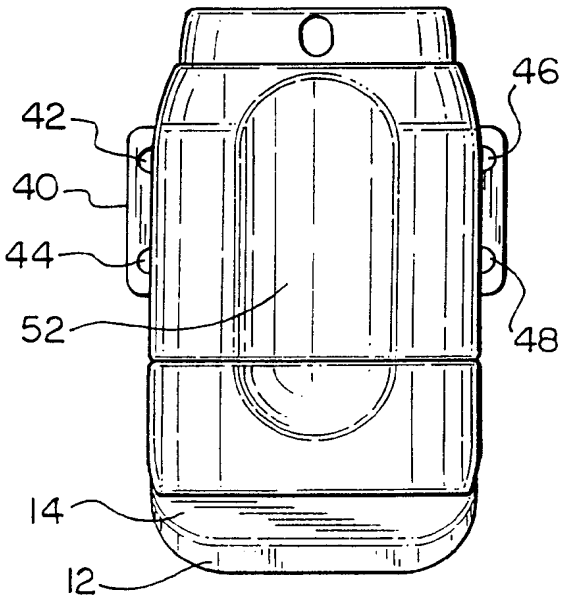

FIG. 4

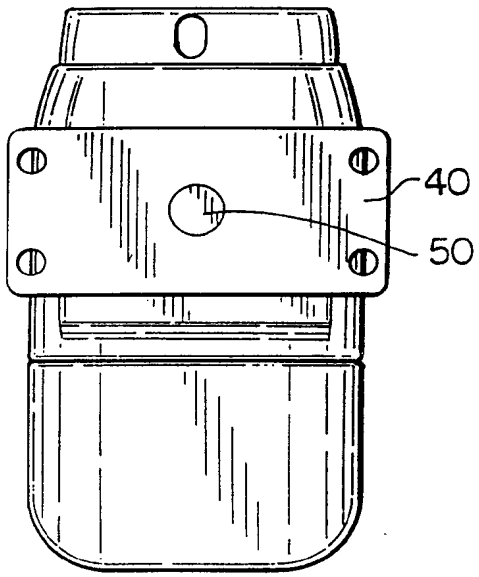

FIG. 5

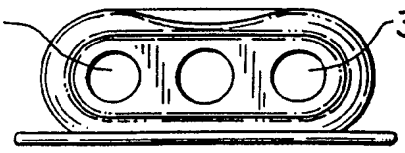

FIG. 6

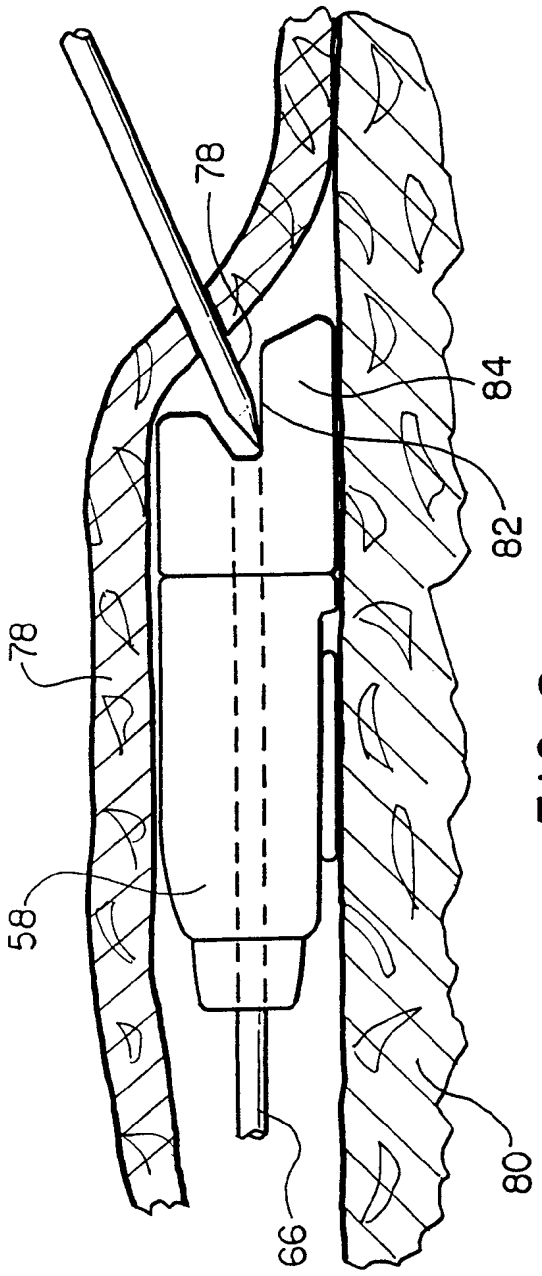

FIG. 9

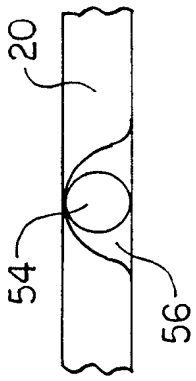

FIG. 7

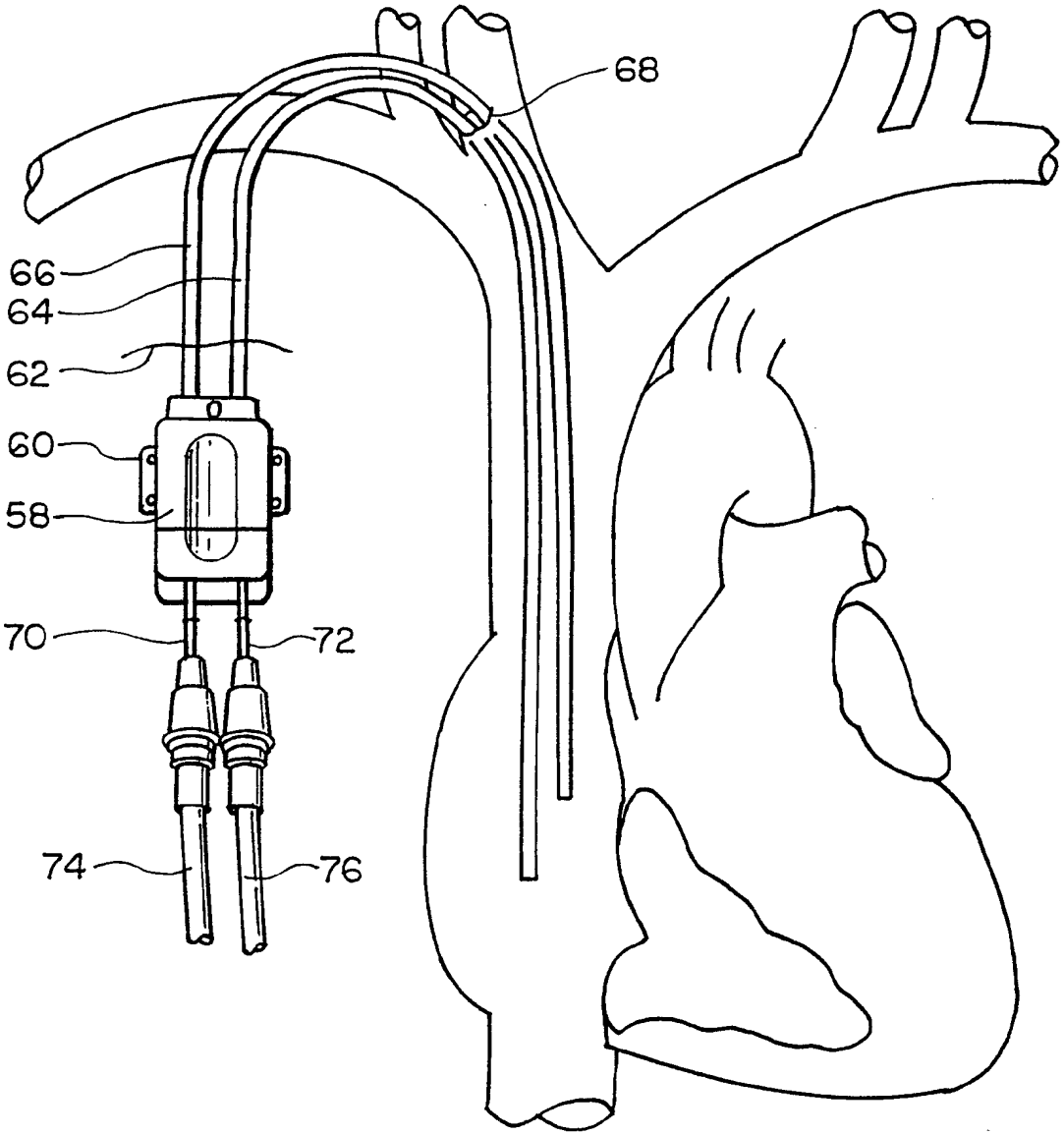

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/14895

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00
US CL :604/96

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/93, 96, 174, 175, 891.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---P Y	US 5,911,706 A (ESTABROOK et al.) 15 June 1999, entire document, figures, and filing date.	1, 2, 5-7, 11-20 --- 3, 4, 8-10
Y	US 5,527,278 A (ENSMINGER et al.) 18 June 1996, entire document, Fig. 9, and more patents by this author.	3, 4, 8-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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